UNITED NATIONS

E/NL. 1990/26-28
17 August 1990
ENGLISH ONLY

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

PHILIPPINES

Communicated by the Government of the Philippines

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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E/NL.1990/26

BOARD REGULATION No. 5 s. 1989, 17 August 1989

INCLUSION OF BUPRENORPHINE AND PEMOLINE; THEIR SALTS, ISOMERS, AND SALTS OF ISOMERS; AND COMPOUNDS, MIXTURES, AND PREPARATIONS CONTAINING SUCH SUBSTANCES IN THE LIST OF DANGEROUS DRUGS

Section 1

Pursuant to its powers under section 36 (a) of Republic Act No. 6425, as amended, 1/ the Dangerous Drugs Board, finding after evaluation that the following substances:

International Non-proprietary name (INN)	Chemical name 2/	Other name
BUPRENORPHINE		Temgesic Buprenex
PEMOLINE		Phenoxazole Phenylisohydantoin Phenylpseudohydantoin

have the capacity to produce dependence and are likely to be so abused as to constitute a public health and social problem, which finding is in agreement with the decisions of the United Nations Commission on Narcotic Drugs identified as 1(XXXIII) and 2(XXXIII), hereby classified as Dangerous Drugs and further categorized as Regulated Drugs, the said substances as well as their salts, isomers (whether optical, position, or geometric) which (a) exist within the specific chemical designations by whatever official name, common name or usual name, chemical name or brand name and (b) have the same or similar psychologic and/or physiologic effects as the parent drugs mentioned above.

Section 2

All compounds, mixtures, or preparations containing these substances and their salts, isomers, and salts of isomers qualified in section 1 hereof are classified as Dangerous Drugs and further categorized as Regulated Drugs.

Section 3

In view of this classification, these dangerous drugs shall be subject to all control measures in article III, "Regulated Drugs" and article IV, "Provisions of Common Application to Offenses Penalized under articles II and III" of Republic Act 6425, as amended, 1/ and pertinent regulations issued by the Dangerous Drugs Board.

Section 4

Any violation hereof shall be a ground for administrative action, without prejudice to the filing of a criminal case, if warranted in the premises.

Section 5

This regulation supplements Board Regulation No. 6, Series of 1972 3/ and shall take effect fifteen (15) days after its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for
Standards and Regulation)

(Signed)

E/NL.1990/27

BOARD REGULATION No. 7 s. 1989, 19 October 1989

PROVIDING GUIDELINES FOR THE IMPLEMENTATION OF BOARD REGULATIONS WHEREIN CERTAIN PROVISIONS OF THE GENERICS ACT OF 1988 (R.A. 6675) ARE APPLICABLE

Pursuant to the powers of the Board under section 36 (a) of R.A. 6425, as amended, 1/ in relation to section 9 and section 6 (a) and (b) of The Generics Act of 1988, the following guidelines are hereby prescribed:

Section 1

For Practitioners:

In issuing a prescription, a duly authorized practitioner shall indicate therein the generic name of the dangerous drug or exempt dangerous drug preparation prescribed. He shall also comply with the conditions set forth in section 3 of Administrative Order No. 62, Series of 1989 of the Department of Health.

Section 2

For manufacturers, compounders, exporters and importers:

They shall indicate the generic name on the label of the dangerous drugs or exempt dangerous drug preparations which they deal on. They shall also comply with Administrative Order No. 55, Series of 1989 of the Department of Health.

Section 3

For drug outlets:

Drug outlets dispensing dangerous drugs and exempt dangerous drug preparations shall practice generic dispensing and shall comply with the conditions set forth in section 3 of Administrative Order No. 63, S. 1989 of the Department of Health, except the provision of section 3, paragraph 3.1.1.2, which is, posting in a conspicuous place in their establishment a list of drug products using generic names with their brand names.

They shall also comply with the provisions of Board Regulation No. 11, Series of 1973 governing the partial filing of dangerous drugs. 4/

Section 4

Prohibition against advertising:

Dangerous drugs and exempt dangerous drug preparations shall not be advertised to the general public. They may, however, be advertised in scientific journals.

Section 5

Prohibition against distribution of samples:

Dangerous drugs and exempt dangerous drug preparations shall not be distributed as samples.

Section 6

Report of violations:

Violations of this regulation shall be reported to the Department of Health for appropriate action.

Section 7

Repealing clause:

All rules and regulations inconsistent herewith shall be deemed repealed or modified accordingly.

READEX

Section 8

Effectivity:

This regulation shall take effect after its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for
Standards and Regulation)

(Signed)

E/NL.1990/28

BOARD REGULATION No. 9 s. 1989, 19 October 1989

EXEMPT REGULATED PREPARATIONS

Pursuant to the powers of the Dangerous Drugs Board under section 36 (a), article VIII of R.A. 6424, as amended, 1/ the following regulation is hereby prescribed:

Section 1

Definition of terms:

(a) "Dangerous Drug Preparation" refers to any solution or mixture, in whatever physical state, containing:

(1) one or more dangerous drugs; or

(2) one or more dangerous drugs in dosage form.

As herein construed, a dangerous drug preparation is in dosage form when it consists of a measured, small quantity of dangerous drugs or a combination of dangerous drugs in whatever form (tablet or pill, ampoule or powder) ready for consumption by, or administration to, a patient or animal, whether orally or parenterally or through other routes.

(b) "Exempt Dangerous Drug Preparation" is any dangerous drug preparation which is compounded in such a way that it presents no, or a negligible, risk of abuse and the dangerous drug it contains cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem; and has high therapeutic value, a wide use for legitimate purposes and is a much needed medicine required to be easily available to the public in medical need thereof. The word "compounded" as herein used means the process of combining a controlled drug with a non-controlled ingredient counteractive of the abuse liability of the controlled drug present.

(1) "Exempt Regulated Drug Preparation" is any dangerous drug preparation which:

(i) contains only one regulated drug internationally controlled under Schedules III or IV of the 1971 Convention on Psychotropic Substances and not exceeding the quantitative limits for such as determined by the Board;

(ii) is not a combination of a regulated drug with a prohibited drug;

(iii) is not a combination of a psychotropic drug under international control with an uncontrolled drug having similar psychotropic properties;

(iv) does not contain any psychotropic substance listed in Schedule II annexed to the 1971 Convention on Psychotropic Substances;

(v) includes one or more non-narcotic or non-psychotropic active medicinal ingredients in proportion sufficient to confer upon the preparation valuable medicinal properties other than those possessed by the regulated drug alone and to prevent enhancement, potentiation or synergism of the abuse liability of the regulated drug (or any of its salts) that it contains; or if it consists of a single psychotropic substance in dosage form, is compounded with a counteracting non-psychotropic or non-narcotic material;

(vi) is devoid of any prohibited drug under Schedule IV of the 1961 Convention on Narcotic Drugs or another psychotropic drug not under domestic or international control but with known abuse potential; and

(vii) is not in injectable form.

This last criterion does not apply when the preparation has high therapeutic usefulness. As herein construed, a preparation in injectable form is deemed to have high therapeutic usefulness if it is very effective for the indicated use, is safely administered by skilled professionals and is widely used in medicine.

Section 2

Jurisdiction:

The dangerous Drugs Board has jurisdiction and control over all exempt dangerous drug preparations except where registration of the product and determination of its efficacy, purity and safety are concerned which are within the functions of the Bureau of Food and Drugs under R.A. 3720, as amended.

Section 3

Control measures not required for Exempt Regulated Preparations:

Exempt regulated preparations are not subject to the following control measures:

(a) Compulsory use of DDB Form 1-72 or Yellow Prescription.

The preparation shall, however, be prescribed through an Ordinary Prescription wherein the S-2 licence of the practitioner shall be indicated.

(b) Recording in the Dangerous Drugs Record Book.

The preparation should, however, be recorded in the Additional Dangerous Drugs Record Book.

Section 4

Effect of the presence of a prohibited drug:

When the exempt regulated preparation is compounded with a prohibited drug, the preparation shall be deemed to be a prohibited drug.

Section 5

Prohibition against sample distribution:

Exempt regulated drug preparation shall not be distributed as samples to the practitioners or to the general public.

Section 6

Advertising:

Exempt dangerous drug preparations may be advertised in scientific journals. In no case, however, shall such preparations be advertised to the general public.

Section 7

Sanctions:

Any individual or entity found, after notice and hearing, guilty of violating this regulation shall be penalized with the sanctions embodied in section 36 (1), article VIII of Republic Act No. 6425, as amended, 1/ without prejudice to the institution of criminal proceedings if circumstances so warrant.

Section 8

Repealing clause:

All regulations inconsistent herewith are hereby repealed or modified accordingly.

Section 9

Effectivity:

This regulation shall take effect after the completion of its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for
Standards and Regulation)

(Signed)

Notes by the Secretariat

1/ E/NL.1982/43.

2/ Chemical names given in the text were identical to those which appear in the international drug control treaties and are accordingly not reproduced.

3/ E/NL.1976/55.

4/ E/NL.1976/67.

UNITED NATIONS

E/NL. 1990/29
22 August 1990

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UNITED STATES OF AMERICA

Communicated by the Government of the United States of America

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FINAL RULE IMPLEMENTING THE CHEMICAL DIVERSION AND TRAFFICKING ACT OF 1988 1/

PARTS 1310 AND 1313

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Sec.
1310.01 Definitions.
1310.02 Substances covered.
1310.03 Persons required to keep records and file reports.
1310.04 Maintenance of records.
1310.05 Reports.
1310.06 Content of records and reports.
1310.07 Proof of identity.

AUTHORITY: 21 U.S.C. 802, 830, 871(b).

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act, as amended (84

*) Note by the Secretariat: The present document is a direct reproduction of the text communicated to the Secretariat.

1/ Note by the Secretariat: E/NL.1989/27.

Stat. 1242; 21 U.S.C. 801)[1] and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

(b) The term "listed chemical" means any listed precursor chemical or listed essential chemical.

(c) The term "listed precursor chemical" means a chemical specifically designated by the Administrator in § 1310.02(a) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of this title and is critical to the creation of a controlled substance.

(d) The term "listed essential chemical" means a chemical specifically designated by the Administrator in § 1310.02(b) that, in addition to legitimate uses, is used as a solvent, reagent, or catalyst in manufacturing a controlled substance in violation of this title.

(e) The term "regulated person" means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine.

(f) The term "regulated transaction" means:

(1) A distribution, receipt, sale, importation or exportation of a threshold amount as determined by the Administrator which includes a cumulative threshold amount for multiple transactions of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part of Part 1313 of this chapter;

(iii) Any category of transaction specified by regulation of the Administration as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or

(v) Any transaction in a chemical mixture.

(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(g) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a listed precursor chemical or listed essential chemical, except that such term does not include any combination of a listed precursor chemical or a listed essential chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

(h) The term "retrievable" means that records required by this section are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be readily retrieved and separated out from all other records in a reasonable time and/or records are kept on which the listed chemicals, tableting machines, and encapsulating machines are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records or the maintained separate from all other records.

(i) The term "tableting machine" means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding

of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

(j) The term "encapsulating machine" means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

(k) Any term not defined in this section shall have the definition set forth in section 102 and 1001 of the Act (21 U.S.C. 802 and 951) and § 1301.02 of this chapter.

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and Part 1313 of this chapter.

(a) Listed Precursor Chemicals:

(1) Anthranilic acid and its salts

(2) Benzyl cyanide

(3) Ephedrine, its salts, optical isomers, and salts of optical isomers

(4) Ergonovine and its salts

(5) Ergotamine and its salts

(6) N-Acetylanthranilic acid and its salts

(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers

(8) Phenylacetic acid and its salts

(9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers

(10) Piperidine and its salts

(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

(12) 3,4-Methylenedioxyphenyl-2-propanone

(b) Listed Essential Chemicals:

(1) Acetic anhydride

(2) Acetone

(3) Benzyl chloride

(4) Ethyl ether

(5) Hydriodic acid

(6) Potassium permanganate

(7) 2-Butanone (or Methyl Ethyl Ketone or MEK)

(8) Toluene

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

(1) The name and address of the petitioner;

(2) The name of the chemical to which the petition pertains;

(3) The name and address of the manufacturer(s) of the chemical (if known);

(4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;

(5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

§ 1310.03 Persons required to keep records and file reports.

Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05.

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a listed precursor chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for four years after the date of the transaction.

(b) Every record required to be kept subject to § 1310.03 for a listed essential chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) The quantitative threshold or the cumulative amount for multiple transactions within a calendar month to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

(1) Listed Precursor Chemicals:

Chemical	Threshold by base weight
(i) Anthranilic acid and its salts	30 kilograms.
(ii) Benzyl cyanide	1 kilogram.
(iii) Ephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(iv) Ergonovine and its salts	10 grams.
(v) Ergotamine and its salts	20 grams.
(vi) N-Acetylanthranilic acid and its salts	40 kilograms.
(vii) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(viii) Phenylacetic acid and its salts	1 kilogram.
(ix) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(x) Piperidine and its salts	500 grams.
(xi) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(xii) 3,4-Methylenedioxyphenyl-2-propanone	20 kilograms.

(2) Listed Essential Chemicals:

(i) Imports and Exports

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	500 gallons	1,500 kilograms.
(C) Benzyl chloride	N/A	4 kilograms.
(D) Ethyl ether	500 gallons	1,364 kilograms.
(E) Hydriodic acid	40 liters (57%)	22.8 kilograms.
(F) Potassium permanganate	N/A	500 kilograms.
(G) 2-Butanone (MEK)	500 gallons	1,455 kilograms.
(H) Toluene	500 gallons	1,591 kilograms.

(ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	50 gallons	150 kilograms.
(C) Benzyl chloride	N/A	1 kilogram.
(D) Ethyl ether	50 gallons	135.8 kilograms.
(E) Hydriodic acid	10 liters (57%)	5.7 kilograms.
(F) Potassium permanganate	N/A	55 kilograms.
(G) 2-Butanone (MEK)	50 gallons	145 kilograms.
(H) Toluene	50 gallons	159 kilograms.

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

§ 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

(3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in § 1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

§ 1310.06 Content of records and reports.

(a) Each record required by § 1310.03 shall include the following:

(1) The name and address of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model and serial number).

(4) The method of transfer (company truck, picked up by customer, etc.).

(5) The type of identification used by the purchaser and any unique number on that identification.

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person.

(c) Each report required by § 1310.05 shall include the information as specified by § 1310.06(a) and, where obtainable, the telephone number of the other party. A report submitted pursuant to § 1310.05(a)(1) or (a)(3) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under § 1310.05(a)(3), the circum-

stances of such loss must be provided (in-transit, theft from premises, etc.).

(d) A suggested format for the reports is provided below:

Supplier:
Name ———————————
Business Address ———————————
City ———————————
State———————————
Zip———————————
Business Phone ———————————
Purchaser:
Name ———————————
Business Address ———————————
City ———————————
State———————————
Zip———————————
Business Phone ———————————
Identification ———————————
Shipping Address (if different than purchaser address):
Street ———————————
City ———————————
State———————————
Zip———————————
Date of Shipment ———————————
Name of Listed Chemical(s)———————————
Quantity and Form of Packaging ———————————
Description of Machine:
Make: ———————————
Model: ———————————
Serial # ———————————
Method of Transfer ———————————
If Loss or Disappearance:
Date of Loss ———————————
Type of Loss———————————
Description of Circumstances———————————

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, DC 20503.

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transactions, this shall be accomplished by having the other party present documents which would verify the identity of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm's listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity.

(c) When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative.

(d) For sales to individuals or cash purchasers, the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver's license and one other form of identification. Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person shall diligently obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport

information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

(e) For a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

(f) With respect to electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders and with § 1310.07(e).

[...]

PART 1313—IMPORTATION AND EXPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS

Sec.

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IMPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS

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AUTHORITY: 21 U.S.C. 802, 830, 871(b), 971.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of precursors and essential chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

§ 1313.02 Definitions.

(a) The term "chemical export" means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

(b) The term "chemical exporter" is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

(c) The term "regulated person" means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term "regulated transaction" means:

(1) A distribution, receipt, sale, importation or exportation of a threshold amount as determined by the Administrator which includes a cumulative threshold amount for multiple transactions of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and conttol of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part of Part 1310;

(iii) Any category of transaction specified by regulation of the Administration as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or

(v) Any transaction in a chemical mixture.

(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(e) The term "chemical import" means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(f) The term "chemical importer" is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

(g) The term "regular customer" means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in § 1313.02(j).

(h) The term "regular supplier" means a supplier with whom the regulated person has an established business relationship that has been reported to the Administration subject to the criteria established in § 1313.02(i).

(i) The term "established business relationship with a regular supplier" means the regulated person has purchased a listed chemical from a foreign supplier at least once within the past six months, or twice within the past twelve months. The term also means that the regulated person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.15:

(1) The name, street address, telephone number, telex number and, where available, the facsimile number of the chemical importer and of each regular supplier; and

(2) The frequency and number of transactions occurring during the preceding 12-month period.

(j) The term "established business relationship with a foreign customer" means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer within the meaning of this section. The term also means that the regulated person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.24:

(1) The name and street address of the chemical exporter and of each regular customer;

(2) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(3) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(4) The duration of the business relationship;

(5) The frequency and number of transactions occurring during the preceding 12-month period;

(6) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and the regular customer;

(7) The method of delivery (direct shipment or through a broker or forwarding agent); and

(8) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(k) The term "Customs territory of the United States" means the several states, the District of Columbia, and Puerto Rico.

(l) The term "jurisdiction of the United States" means the Customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and Palau.

(m) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951), and §1301.02 and § 1310.01 of this chapter.

Importation of Precursors and Essential Chemicals

§ 1313.12 Requirement of authorization to import.

(a) Each regulated person who imports a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter shall notify the Administrator of the importation not later than 15 days before the transaction is to take place.

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the importation:

Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Drug Control Section, through electronic facsimile media not later than 15 days prior to the importation.

(c) The 15-day advance notification requirement for listed chemical imports may be waived for any regulated person who has satisfied the requirements for reporting to the Administration an established business relationship with a foreign supplier. For such imports, the DEA Form 486 must be received by the Drug Enforcement Administration, Drug Control Section on or before the date of importation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

§ 1313.13 Contents of import declaration.

(a) Any precursor or essential chemical listed in § 1310.02 of this chapter may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United States. Chemical importations into the United States for immediate transfer/transshipment outside the United States must comply with the procedures set forth in § 1313.31.

(b) Any regulated person who desires to import a threshold or greater quantity of a listed chemical shall notify the Administration through procedures set forth in § 1313.12 and distribute three copies of DEA Form 486 as directed in § 1313.14.

(c) The DEA Form 486 must be executed in triplicate and must include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical importer; the name, address, telephone, telex, and where available, the facsmile number of the broker or forwarding agent (if any); and

(2) The name and description of each listed chemical as it appears on the label or container, the name of each chemical as it is designated in 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof; and the gross weight of the shipment given in kilograms or parts thereof; and

(3) The proposed import date, the foreign port of exportation and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsmile number of the consignor in the foreign country of exportation.

§ 1313.14 Distribution of import declaration.

The required three copies of the precursor and essential chemical import declaration (DEA Form 486) will be distributed as follows:

(a) Copy 1 shall be retained on file by the regulated person as the official record of import. Import declaration forms involving a listed precursor chemical must be retained for four years; declaration forms for listed essential chemicals must be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 6053 of the Chemical Diversion and Trafficking Act of 1988, as specified in § 1313.12.

(c) Copy 3 shall be presented to the U.S. Customs Sevice along with the customs entry. If the import is a regulated transaction for which the 15-day advance notice requirement has been waived, the regulated person shall declare this information to the U.S. Customs Service Official by checking the block on the DEA Form 486 designated for this purpose.

§ 1313.15 Waiver of 15-day advance notice for chemical importers.

(a) Each regulated person shall provide to the Administration the identity of any regular supplier of the regulated person not later than August 31, 1989, along with the information required by § 1313.02(i) for documenting an established business relationship with a regular supplier.

(b) Not later than October 30, 1989, each regular supplier so identified in notifications made under paragraph (a) of this section shall be a regular supplier for purposes of waiving the 15-day advance notice requirement,

unless the regulated person is otherwise notified in writing by the Administration.

(c) A supplier identified on an initial DEA Form 486 submitted after October 30, 1989, shall, after the expiration of the 15-day period, qualify as a regular supplier, unless the Administration otherwise notifies the regulated person in writing.

(d) All chemical importers shall be required to file a DEA Precursor and Essential Chemical Import/Export Declaration (DEA Form 486) as required by § 1313.12.

EXPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS

§ 1313.21 Requirement of authorization to export.

(a) No person shall export of cause to be exported from the United States any chemical listed in § 1310.02 of this chapter, which meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter until such time as the Administrator has been notified. Notification must be made not later than 15 days before the transaction is to take place. In order to facilitate the export of listed chemicals and implement the purpose of the Act, regulated persons may wish to provide notification to the Administration as far in advance of the 15 days as possible.

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the exportation:

Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Drug Control Section, through electronic facsimile media not later than 15 days prior to the exportation.

(c) The 15-day advance notification requirement for listed chemical exports may be waived for any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship with a foreign customer as defined in § 1313.02(j). A DEA Form 486 export declaration to a foreign customer must be received by the Drug Enforcement Administration, Drug Control Section, on or before the date of exportation through use of the mailing address listed in § 1313.21(b) or transmitted directly through use of electronic facsimile media.

(d) No person shall knowingly or intentionally export or cause to be exported a listed chemical in violation of the law of the country to which the chemical is exported. Likewise, no person shall export or cause to be exported any listed chemical when that person has reasonable cause to believe the regulated transaction is in violation of the law of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

§ 1313.22 Contents of export declaration.

(a) Any precursor or essential chemical listed in § 1310.02 of this chapter which meets or exceeds the quantitative threshold criteria established in § 1310.04(f) of this chapter may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any regulated person who desires to export a threshold or greater quantity of a listed chemical shall notify the Administration through procedures outlined in § 1313.21 and distribute three copies of DEA Form 486 as directed in § 1313.23.

(c) The DEA Form 486 must be executed in triplicate and must include all the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, telex number, and, where available, the facsimile number of the export broker, if any;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of

the shipment given in kilograms or parts thereof;

(3) The proposed export date, the U.S. Customs port of exportation, and the foreign port of entry; and

(4) The name, address, telephone, telex, and where available, the facsimile number of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

(d) Notwithstanding the time limitations included in paragraph (b) of this section, a regulated person may receive a waiver of the 15-day advance notification requirement following the procedures outlined in § 1313.24.

(e) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. chemical exporter of record. A brief written notification (this does not require a DEA Form 486) outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038, following the return within a reasonable time. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

§ 1313.23 Distribution of export declaration.

The required three copies of the precursor and essential chemical export declaration (DEA Form 486) will be distributed as follows:

(a) Copy 1 shall be retained on file by the chemical exporters as the official record of export. Export declaration forms involving a listed precursor chemical must be retained for four years; declaration forms for listed essential chemicals must be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 6053 of the Chemical Diversion and Trafficking Act of 1988, as specified in § 1313.21

(c) Copy 3 shall be presented to the U.S. Customs Service at the port of exit along with the Shippers Export Declaration for each export of a listed chemical or chemicals.

§ 1313.24 Waiver of 15-day advance notice for chemical exporters.

(a) Each regulated person shall provide to the Administration the identity and information listed in § 1313.02(j) for an established business relationship with a foreign customer not later than August 31, 1989.

(b) Not later than October 31, 1989, each regular customer so identified in notifications made under § 1313.24(a) shall be a regular customer for purposes of waiving the 15-day advance notice requirement, unless the regulated person is otherwise notified in writing by the Administration.

(c) Each foreign customer identified on an initial DEA Form 486 submitted after the effective date of the implementation of Part 1313 shall, after the expiration of the 15-day period, qualify as a regular customer, unless the Administration otherwise notifies the regulated person in writing.

(d) The Administrator may notify any chemical exporter that a regular customer has been disqualified or that a new customer for whom a notification has been submitted is not to be accorded the status of a regular customer. In the event of a disqualification of an established regular customer, the chemical exporter will be notified in writing of the reasons for such action.

Public reporting (one-time) burden for this collection of information is estimated to average four hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing and collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0025, Washington, DC 20503.

§ 1313.25 Foreign import restrictions.

Any export from the United States in violation of the law of the country to which the chemical is exported is subject to the penalties of Title 21 United States Code 960(d).

§ 1313.31 Advance notice of importation for transshipment or transfer.

(a) A quantity of a chemical listed in § 1310.02 of this chapter that meets or exceeds the threshold reporting requirements found in § 1310.04(f) of this chapter may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that advance notice is given to the Administration.

(b) Advance notification must be provided to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038, not later than 15 days prior to the proposed date the listed chemical will transship or transfer through the United States. The written notification (not a DEA Form 486) shall contain the following information:

(1) The date the notice was executed;

(2) The complete name and description of the listed chemical as it appears on the label or container.

(3) The name of the listed chemical as designated by § 1310.02 of this chapter.

(4) The number of containers and the size or weight of the container for each listed item;

(5) The new weight of each listed chemical given in kilograms or parts thereof;

(6) The gross weight of the shipment given in kilograms or parts thereof;

(7) The name, address, telephone number, telex number, business of the foreign exporter and, where available, the facsimile number;

(8) The foreign port of exportation;

(9) The approximate date of exportation;

(10) The complete identification of the exporting carrier;

(11) The name, address, business, telephone number, telex number, and, where available, the facsimile number of the importer, transferor, or transshipper;

(12) The U.S. port of entry;

(13) The approximate date of entry;

(14) The name, address, telephone number, telex number, business of the consignee and, where available, facsimile number of the consignee at the foreign port of entry;

(15) The shipping route from the U.S. port of exportation to the foreign port of entry at final destination;

(16) The approximate date of receipt by the consignee at the foreign port of entry; and

(17) The signature of the importer, transferor or transshipper, or his agent, accompanied by the agent's title.

(c) Unless notified to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved.

(d) No waiver of the 15-day advance notice will be given for imports of listed chemicals in quantities meeting or exceeding threshold quantities for transshipment or transfer outside the United States.

§ 1313.41 Suspension of shipments.

(a) The Administrator may suspend any importation or exportation of a chemical listed in § 1310.02 of this chapter based on evidence that the chemical proposed to be imported or exported may be diverted to the clandestine manufacture of a controlled substance. If the Administrator so suspends, he shall provide written notice of such suspension to the regulated person. Such notice shall contain a statement of the legal and factual basis for the order.

(b) Upon service of the order of suspension, the regulated person to whom the order applies under paragraph (a) of this section must, if he desires a hearing, file a written request for a hearing pursuant to §§ 1313.51—1313.57.

HEARINGS

§ 1313.51 Hearings generally.

In any case where a regulated person requests a hearing regarding the suspension of a shipment of a listed chemical, the procedures for such hearing shall be governed generally by the procedures set forth in the

Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 6053 of the Chemical Diversion and Trafficking Act (Pub. L. 100-690), by 21 CFR 1313.52—1313.57, and by the procedures for administrative hearings under the Controlled Substances Act set forth in §§ 1316.41-1316.67 of this chapter.

§ 1313.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall cause a hearing to be held for the purpose of receiving factual evidence regarding the issues involved in the suspension of shipments within 45 days of the date of the request, unless the requesting party requests an extension of time.

§ 1313.53 Waiver of modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1313.54 Request for hearing.

(a) Any person entitled to a hearing pursuant to § 1313.52 and desiring a hearing shall, within 30 days after receipt of the notice to suspend the shipment, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) If any person entitled to a hearing or to participate in a hearing pursuant to § 1313.41 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(c) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1313.57.

§ 1313.55 Burden of proof.

At any hearing regarding the suspension of shipments, the Agency shall have the burden of proving that the requirements of this part for such suspension are satisfied.

§ 1313.56 Time and place of hearing.

(a) If any regulated person requests a hearing on the suspension of shipments, a hearing will be scheduled no later than 45 days after the request is made, unless the regulated person requests an extension to this date.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1313.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order regarding the suspension of shipment. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon each party in the hearing.